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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DELLA, JAYMI E

ART UNIT

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4137

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,596	<b>Applicant(s)</b> FALWELL ET AL.	
	<b>Examiner</b> JAYMI DELLA	<b>Art Unit</b> 4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43, 74 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 44-73 and 75-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43, 74 and 95 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-15**, drawn to an electrophysiology catheter with a tip assembly bias means of superelastic material with a cable for changing the orientation of the tip assembly.

**Group II, claim(s) 16-31**, drawn to an electrophysiology catheter with a tip assembly bias means of adhesive.

**Group III, claim(s) 32**, drawn to an electrophysiology catheter with a tip assembly bias means of adhesive and two cables for changing the orientation of the tip assembly.

**Group IV, claim(s) 33-36**, drawn to an electrophysiology catheter with a tip assembly and proximal tip end bias means of adhesive and two cables for changing the orientation of the tip assembly .

**Group V, claim(s) 37**, drawn to a method of shaping a tip assembly with adhesive to bias the tip.

**Group VI, claim(s) 74**, drawn to an electrophysiology catheter body bias means of superelastic material.

**Group VII, claim(s) 95**, drawn to an electrophysiology catheter with a catheter body bias means of superelastic material.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common

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technical feature between Groups I, II, III, IV, V, VI, and VII is a biasing means for the catheter. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Koblish et al. (WO/2001/037723) disclose an electrophysiology catheter with a biasing means for an adjustable electrode portion at the distal end. The catheter includes a stylet that causes the electrode portion to increase or decrease in diameter (Page 11, Lines 8-17). Therefore, this feature cannot be a special technical feature under PCT Rule 13.2 because it fails to provide contribution to the prior art. Hence, a holding that, these groups do not have a single general inventive concept is proper.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

### **Electrode Configurations**

#### **Set I:**

**Species A:** Electrodes are uniformly spaced apart on the distal end of the tip assembly (Page 17, Lines 9-10).

**Species B:** Electrodes are grouped in pairs, with the distance between each electrode of a pair being closer than the distance between electrodes of adjacent pairs (Page 17, Lines 11-13).

#### **Set II:**

**Species A:** Electrodes are recessed (low-profile electrodes) within the outer circumferential surface of the distal section (Page 25, Lines 4-6; Fig. 15).

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**Species B:** Electrodes protrude (raised profile electrodes) above the outer circumferential surface of the distal section (Page 25, Line 7-8; Fig. 15A).

**Species C:** A combination of raised and low-profile electrodes is used (Page 38, Line 16).

**Set III:**

**Species A:** Electrodes are fixed in position (Page 39, Line 3)

**Species B:** Electrodes are movable along the length of the distal end of the tip assembly as illustrated in Fig. 18.

**Set IV:**

**Species A:** Tip assembly includes a conductive cap electrode (Page 22, Line 28).

**Species B:** Tip assembly includes a non-conductive cap (Page 22, Line 29).

**Set V:**

**Species A:** Tip assembly includes a threaded collar secured to the distal end of the distal section to retain a distal cap (Page 22, Lines 26-27).

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**Species B:** Tip assembly does not include a threaded collar secured to the distal end of the distal section to retain a distal cap (Page 22, Lines 28-29).

**Tip Assembly – Radius of Curvature**

**Set VI:**

**Species A:** The radius of curvature bias is controlled only by a pair of cables as illustrated in Fig. 11-13.

**Species B:** The radius of curvature bias is controlled by one cable and a superelastic wire as illustrated in Fig. 38-39B.

**Subset I:**

**Sub-species A:** Superelastic wire is disposed within the lumen on the inner side of the radius of curvature of the tip assembly (Page 26, Line 26-28; Fig. 38-29B).

**Sub-species B:** Superelastic wire is disposed within the lumen on the outer side of the radius of curvature of the tip assembly (Fig. 41A-B).

**Sub-species C:** Superelastic wire is disposed within central lumen (Page 26, Line 30).

**Sub-species D:** Superelastic wire is embedded within the core of the tip assembly (Page 26, Line 31).

**Subset II:**

**Sub-species A:** Superelastic wire is anchored at the most distal end of the tip assembly and tied together with the cable (Page 26, Line 32 through Page 27, Line 1).

**Sub-species B:** Superelastic wire is not anchored and not tied to the cable (Page 27, Lines 2-5).

**Subset III:**

**Sub-species A:** Superelastic is wire biased in an arcuate curve as illustrated in Fig. 45.

**Sub-species B:** Superelastic wire is biased linearly as illustrated in Fig. 43A.

**Species C:** The radius of curvature bias is controlled by one cable and adhesive as illustrated in Fig. 45-46B.

**Subset I:**

**Sub-species A:** Adhesive is disposed within the lumen on the inner side of the radius of curvature of the tip assembly (Page 26, Line 26-28; Fig. 45).

**Sub-species B:** Adhesive is disposed within central lumen  
(Page 28, Line 30).

**Sub-species C:** Adhesive is disposed within the lumen on  
the outer side of the radius of curvature of the tip assembly  
(fig. 48AB).

**Subset II:**

**Sub-species A:** Adhesive is biased in an arcuate curve as  
illustrated in Fig. 45.

**Sub-species B:** Adhesive is biased linearly as illustrated in  
Fig. 50A.

**Species D:** The radius of curvature bias is controlled by two cables and  
adhesive as illustrated in Fig. 65B.

**Subset I:**

**Sub-species A:** Adhesive is biased in an arcuate curve as  
illustrated in Fig. 45.

**Sub-species B:** Adhesive is biased linearly as illustrated in  
Fig. 50A.



**Species E:** The radius of curvature bias is controlled by adhesive only as illustrated in Fig. 52-53.

**Active Bend**

**Set VII:**

**Species A:** The distal end tip assembly bend is fixed (Page 31, Line 2).

**Species B:** The distal end tip assembly bend is active (Page 31, Line 4; Fig. 21-21A)

**Subset I:**

**Species A:** The active bend is controlled by a pair of cables (Page 32, Lines 10-15).

**Species B:** The active bend is controlled by one cable and a superelastic wire as illustrated in Fig. 40A-42B.

**Sub-subset I:**

**Sub-species A:** Superelastic wire is disposed on the inside of the bend as illustrated in Fig. 40A-B.

**Sub-species B:** Superelastic wire is disposed on the outside of the bend as illustrated in Fig. 42A-42B.

**Subset II:**

**Sub-species A:** Superelastic wire is biased to form a bend angel as illustrated in Fig. 40A.

**Sub-species B:** Superelastic wire is biased linearly as illustrated in Fig. 44A.

**Species C:** The active bend is controlled by one cable and an adhesive as illustrated in Fig. 47A-B and 49A-B.

**Sub-subset I:**

**Sub-species A:** Adhesive is disposed on the inside of the bend as illustrated in Fig. 47A-B.

**Sub-species B:** Adhesive is disposed on the outside of the bend as illustrated in Fig. 49A-B.

**Subset II:**

**Sub-species A:** Adhesive is biased to form a bend angel (Page 32, Line 7).

**Sub-species B:** Adhesive is biased linearly as illustrated in Fig. 51A.

**Species D:** The active bend is controlled by two cables and an adhesive as illustrated in 64B.

**Sub-subset I:**

**Sub-species A:** Adhesive is disposed on the inside of the bend as illustrated in Fig. 47A-B.

**Sub-species B:** Adhesive is disposed on the outside of the bend as illustrated in Fig. 49A-B.

**Subset II:**

**Sub-species A:** Adhesive is biased to form a bend angel (Page 32, Line 7).

**Sub-species B:** Adhesive is biased linearly as illustrated in Fig. 51A.

**Superelastic Channels**

**Set VIII:**

**Species A:** No superelastic channels are used to impart a bias to a portion of the catheter (Page 35, Line 2).

**Species B:** Superelastic channels are used to impart a bias to a portion of the catheter (Page 35, Line 2)

**Subset I:**

**Sub-species A:** Superelastic channel has a cylindrical shape as illustrated in Fig. 68.

**Sub-species B:** Superelastic channel has a rectangular shape as illustrated in Fig. 69.

**Subset II:**

**Sub-species A:** A low-friction coating is adhered to the interior of the superelastic channel as illustrated in Fig. 68.

**Sub-species B:** The channel itself is formed of a low-friction material (Page 36, Lines 25-26)

**Sub-species C:** A low-friction coating is adhered to the exterior of the pull cable as illustrated in Fig. 69.

**Sub-species D:** The pull cable itself is formed of a low-friction material (Page 36, Lines 25-26)

**Handle**

**Set IX:**

**Species A:** Means for imparting friction on a pull cable is through a plurality of detents formed in the planar rear surface of the handle housing that cooperate with corresponding plurality of detents in the lower surface of the thumbwheel (Page 43, Line 32 through Page 44, Line 2; Fig. 27-28)

**Subset I:**

**Sub-species A:** Balls or bearings are held in the undersurface of the thumbwheel (Page 45, Lines 22-24).

**Sub-species B:** Balls or bearings are held in the detents of the handle (Page 45, Line 25)

**Species B:** Means for imparting friction on a pull cable is through a plurality of ramps contoured on the rear planar surface that correspond to a plurality of complementary shaped ramps on the undersurface of the thumbwheel (Page 45, Line 28-30).

**Species C:** Means for imparting friction includes a ramp disposed on the handle that corresponds to positions on the slide actuator (Page 46, Lines 4-6).

**Species D:** Means for imparting friction includes a ramp disposed within the handle that corresponds to positions on the slide actuator (Page 46, Lines 4-6).

**Set X:**

**Species A:** Handle with a thumbwheel and slide actuator as illustrated in Fig. 1.

**Species B:** Handle with three slide actuators as illustrated in Fig. 29A.

**Species C:** Handle with a third plunger-type actuator as illustrated in Fig. 29B.

**Set XI:**

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**Species A:** Tactile feedback is provided to the user through detents disposed on the outer surface of the handle as illustrated in Fig. 31.

**Species B:** Tactile feedback is provided to the user through detents disposed on the inner surface of the handle as illustrated in Fig. 32.

### **Temperature Sensing and Localization**

#### **Set XII:**

**Species A:** One electromagnetic sensor is provided at the distal end of the tip assembly as illustrated in Fig. 34.

**Species B:** More than one electromagnetic sensor is provided at the distal end of the tip assembly as illustrated in Fig. 54.

### **Fluid Delivery**

#### **Set XIII:**

**Species A:** Lumen configuration as illustrated in Fig. 56 and Fig. 58.

**Species B:** Lumen configuration as illustrated in Fig. 57 and Fig. 59.

#### **Set XIII:**

**Species A:** Fluid delivery is accomplished by coupling a fluid injection manifold to the catheter to introduce fluid as illustrated in Fig. 62A-B.

**Species B:** Fluid delivery is accomplished by coupling a fluid injection manifold to a sheath that includes a fluid delivery lumen as illustrated in Fig. 63.

Applicant is required, in reply to this action, to elect a single species **for each set, subset, and sub-subset** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

**Electrode Configurations**

**Set I:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

**Set II:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

**Species C:** 1-43, 74, 95

**Set III:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

**Set IV:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

**Set V:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

**Tip Assembly – Radius of Curvature**

**Set VI:**

**Species A:** No claims

**Species B:** 1-15, 74, 95

**Subset I:**

**Sub-species A:** 1-10, 12-15, 74, 95

**Sub-species B:** 1-8, 10-15, 74, 95

**Sub-species C:** 1-8, 10, 12-15, 74, 95

**Sub-species D:** 1-8, 10, 12-15, 74, 95



**Subset II:**

**Sub-species A:** 1-15, 74, 95

**Sub-species B:** 1-15, 74, 95

**Subset III:**

**Sub-species A:** 1-11, 13-15, 74, 95

**Sub-species B:** 1-15, 74, 95

**Species C:** 16-23, 25-26, 28-31, 37-43

**Subset I:**

**Sub-species A:** 16-23, 25-26, 28, 30-31, 37-43

**Sub-species B:** 16-23, 25-26, 30-31, 37-43

**Sub-species C:** 16-23, 25-26, 29-31, 37-43

**Subset II:**

**Sub-species A:** 16-23, 25-26, 28-29, 31, 37-39, 41-43

**Sub-species B:** 16-17, 19, 25-26, 28-31, 37-38, 40-43

**Species D:** 16-31, 32-33, 37

**Subset I:**

**Sub-species A:** 16-29, 31-33, 37

**Sub-species B:** 16-17, 19, 25-31, 33, 37

**Species E:** 16-18

**Active Bend**

**Set VII:**

**Species A:** 16-18, 37, 74

**Species B:** 1-43, 74, 95

**Subset I:**

**Species A:** None

**Species B:** 1-15, 74, 95

**Sub-subset I:**

**Sub-species A:** 1-15, 74, 95

**Sub-species B:** 1-15, 74, 95

**Subset II:**

**Sub-species A:** 1-15, 74, 95

**Sub-species B:** 1-15, 74, 95

**Species C:** 16-23, 25-26, 28-31, 74

**Sub-subset I:**

**Sub-species A:** 16-23, 25-26, 28-31, 74

**Sub-species B:** 16-23, 25-26, 28-31, 74

**Subset II:**

**Sub-species A:** 16-23, 25-26, 28-29, 74

**Sub-species B:** 16-23, 25-26, 28-31, 74

**Species D:** 1-43, 74

**Sub-subset I:**

**Sub-species A:** 1-43, 74

**Sub-species B:** 1-43, 74

**Subset II:**

**Sub-species A:** 1-43, 74

**Sub-species B:** 1-33, 35-43, 74

**Superelastic Channels**

**Set VIII:**

**Species A:** 1-43

**Species B:** 1-43, 74

**Subset I:**

**Sub-species A:** 1-43, 74

**Sub-species B:** 1-43, 74

**Subset II:**

**Sub-species A:** 1-43, 74

**Sub-species B:** 1-43, 74

**Sub-species C:** 1-43, 74

**Sub-species D:** 1-43, 74

**Handle**

**Set IX:**

**Species A:** 1-43, 74, 95

**Subset I:**

**Sub-species A:** 1-43, 74, 95

**Sub-species B: 1-43, 74, 95**

**Species B: 1-43, 74, 95**

**Species C: 1-43, 74, 95**

**Species D: 1-43, 74, 95**

**Set X:**

**Species A: 1-43, 74, 95**

**Species B: 1-43, 74, 95**

**Species C: 1-43, 74, 95**

**Set XI:**

**Species A: 1-43, 74, 95**

**Species B: 1-43, 74, 95**

**Temperature Sensing and Localization**

**Set XII:**

**Species A: 1-43, 74, 95**

**Species B: 1-43, 74, 95**

**Fluid Delivery**

**Set XIII:**

**Species A: 1-43, 74, 95**

**Species B: 1-43, 74, 95**

**Set XIII:**

**Species A:** 1-43, 74, 95

**Species B:** 1-43, 74, 95

The following claim(s) are generic: None.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they lack the same or corresponding special technical features for the following reasons: the common technical feature between Groups I, II, III, IV, V, VI, and VII is a biasing means for the catheter. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Koblish et al. (WO/2001/037723) disclose an electrophysiology catheter with a biasing means for an adjustable electrode portion at the distal end. The catheter includes a stylet that causes the electrode portion to increase or decrease in diameter (Page 11, Lines 8-17). Therefore, this feature cannot be a special technical feature under PCT Rule 13.2 because it fails to provide contribution to the prior art.

6. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D./

Examiner, Art Unit 4137

June 29, 2009

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111